Criteria for Nonformulary Use of the Non-Calcium, Non-Aluminum Phosphate Binders (Lanthanum Carbonate and Sevelamer Hydrochloride) in VA Patients with Chronic Kidney Disease and Kidney Failure on Dialysis

VA Pharmacy Benefits Management Strategic Healthcare Group and Medical Advisory Panel

The following recommendations are based on current medical evidence and expert opinion from clinicians. The content of the document is dynamic and will be revised as new clinical data becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician should utilize this guidance and interpret it in the clinical context of the individual patient. The manufacturer's labeling and the national drug monographs (www.pbm.va.gov and http://vaww.pbm.va.gov) should be consulted for detailed information when prescribing lanthanum carbonate or sevelamer hydrochloride.

Recommendations

Lanthanum carbonate and sevelamer hydrochloride are restricted to Nephrology Service. These agents are NOT to be used in patients who are not on dialysis.

Criteria for Nonformulary Use of Lanthanum Carbonate or Sevelamer Hydrochloride in Chronic Kidney Disease with Kidney Failure (Stage 5) on Dialysis
Patients must have a diagnosis of Stage 5 CKD (defined as kidney failure with GFR < 15mL/min/1.72m^2 or dialysis) and are receiving kidney replacement therapy (i.e., hemodialysis or peritoneal dialysis) AND one or more of the following:
o Serum phosphorus > 6.5mg/dl (Recommendation: Grade B; QE: Level II-3)[1,2] despite dietary restriction of phosphate to < 1gm/d AND calcium based phosphate binders[a] o Total serum calcium (corrected for serum albumin)[b] ≥ 10.2mg/dl (or maximum per lab/facility) on conventional treatment with calcium based phosphate binding therapy[a] (Recommendation: Grade I; QE: Level III)[3] and despite discontinuation of vitamin D preparations for at least 1 month o Intact plasma parathyroid hormone (PTH) level < 2 times the upper limit of normal for PTH assay (Recommendation: Grade I; QE: Level III)[3] with normal or elevated serum calcium o Calcium x phosphorus product > 55mg^2/dl^2 (Recommendation: Grade B; QE: Level II-2; II-3)[1-4] despite dietary restriction of phosphate to < 1gm/d AND calcium based phosphate binders[a]

QE=Quality of Evidence (Level II-2=well designed cohort or case-control analytic study; Level II-3=multiple time series, dramatic results of uncontrolled experiment; Level III=opinion); Recommendation (Grade B=intervention may be useful/effective; Grade I=insufficient evidence to recommend for or against – the clinician will use their clinical judgment)[5]

[a] An aluminum containing phosphate binder should NOT be used for long-term management of hyperphosphatemia due to potential toxicity. K/DOQI Guideline[3] recommendations are to limit elemental calcium intake from phosphate binders to < 1500mg/d (QE: Level III). In addition, use of 2.5mEq/L calcium dialysate should be part of therapy to reduce hypercalcemia.

[b] Calculation for corrected total serum calcium=total calcium + 0.8 (4 - serum albumin)
[4gm/dl (normal serum albumin) – most recent serum albumin]
Ex. Calcium 9.9mg/dl; albumin 3.2gm/dl
[4 – 3.2] = 0.8; 0.8 X 0.8 = 0.64
9.9 + 0.64 = 10.54 (10.5mg/dl is the corrected serum calcium)

References:

1. Ganesh SK, Stack AG, Levin NW, Hubert-Shearon T, Port FH. Association of elevated serum PO_4, Ca, Ca X PO_4 product, and parathyroid hormone with cardiac mortality risk in chronic hemodialysis patients. J Am Soc Nephrol 2001;12:2131-8.
2. Block GA, Hulbert-Shearon TE, Levin NW, Port FK. Association of serum phosphorus and calcium x phosphorus product with mortality risk in chronic hemodialysis patients: a national study. Am J Kidney Dis 1998;31:607-17.
3. National Kidney Foundation. K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease. Am J Kidney Disease 2003;42(suppl 3):S1-S202.
4. Goodman WG, Goldin J, Kuizon BD, et al. Coronary-artery calcification in young adults with end-stage renal disease who are undergoing dialysis. N Engl J Med 2000;342:1478-83.
5. Harris RP, Helfand M, Woolf SH, et al. for the Methods Work Group, Third U.S. Preventive Services Task Force. Current methods of the U.S. Preventive Services Task Force. A review of the process. Am J Prev Med 2001;20(3S):21-35.

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Updated versions may be found at www.pbm.va.gov or http://vaww.pbm.va.gov